

Docket No. 278292US0PCT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Fabrizio SAMARITANI, et al.

SERIAL NO: 10/551,840

GAU:

FILED: October 3, 2005

EXAMINER:

FOR: LIQUID PHARMACEUTICAL FORMULATIONS OF FSH AND LH TOGETHER WITH A NON-IONIC SURFACTANT

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

**REFERENCES**

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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MAIER & NEUSTADT, P.C.

Norman F. Oblon

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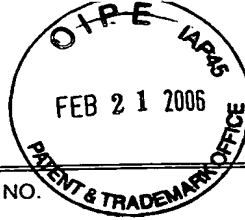
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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 278292US0PCT		SERIAL NO. 10/551,840	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Fabrizio SAMARITANI, et al.			
				FILING DATE October 3, 2005		GROUP	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	5 811 096	09/22/98	ALEMAN et al.			
	AB	6 066 620	05/23/00	MCGREGOR et al.			
	AC	5 650 390	07/22/97	SAMARITANI et al.			
	AD	5 356 876	10/18/94	ESPEY			
	AE	5 929 028	07/27/99	SKRABANJA et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	AF	0 974 359	01/26/00	EP			NO
	AG	0 853 945	07/22/98	EP			NO
	AH	0 318 081	05/31/89	EP			NO
	AI	2 782 455	02/25/00	FR			NO
	AJ	0 603 159	06/22/94	EP			NO
	AK	0 448 146	09/25/91	EP			NO
	AL	1 065 127	04/12/67	GB			NO
	AM	99 21534	05/06/99	WO			NO
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AN	WENZEL et al. "Pluronic F127 gel formulations of Deslorelin and GnRH reduce drug degradation and sustain drug release and effect in cattle", Journal of Controlled Release, vol. 85, pages 51-59 2002					
	AO	NEWMAN et al. "Use of Nonionic Block Copolymers in Vaccines and Therapeutics", Critical Reviews in Therapeutic Drug Carrier Systems, vol. 15, no. 2, pages 89-140 1998					
	AP	BURGUES et al. "Subcutaneous self-administration of highly purified follicle stimulating hormone and human chorionic gonadotrophin for the treatment of male hypogonadotrophic hypogonadism", Human Reproduction, vol. 12, no. 5, pages 980-986 1997					
	AQ	SHOME et al. "A Reevaluation of the Amino Acid Sequence of Human Follicle Stimulating Hormone", Journal of Protein Chemistry, vol. 7, no. 4, pages 325-339 1988					
	AR	KEUTMANN et al. "Structure of Human Luteinizing Hormone Beta Subunit: Evidence for a Related Carboxyl-Terminal Sequence Among Certain Peptide Hormones", Biochemical and Biophysical Research Communications, vol. 90, no. 3, pages 842-848 1979					
	AS	TALMADGE et al. "Evolution of the genes for the beta subunits of human chorionic gonadotropin and luteinizing hormone", Nature, vol. 307, pages 37-40 1984					
	AT	FIDDES et al. "Structure, Expression, and Evolution of the Genes for the Human Glycoprotein Hormones", Recent Progress in Hormone Research, vol. 40, pages 43-78 1984					
	AU	REICHERT et al. "Dissociation of Human Follicle-stimulating Hormone", Journal of Biological Chemistry, vol. 250, no. 8, pages 3034-3040 1975					
	AV	KLEIN et al. "Pharmacokinetics and pharmacodynamics of single-chain recombinant human follicle-stimulating hormone containing the human chorionic gonadotropin carboxyterminal peptide in the rhesus monkey", Fertility and Sterility, vol. 77, no. 6, pages 1248-1255 2002				Additional References sheet(s) attached	
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Form PTO 1449  
(Modified)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

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## LIST OF REFERENCES CITED BY APPLICANT

APPLICANT

Fabrizio SAMARITANI, et al.

FILING DATE

October 3, 2005

GROUP

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	FIDDES et al. "The Gene Encoding the Common Alpha Subunit of the Four Human Glycoprotein Hormones", Journal of Molecular and Applied Genetics, vol. 1, pages 3-18 1981
	AX	MAURER et al. "Isolation and Nucleotide Sequence Analysis of a Cloned cDNA Encoding the beta-Subunit of Bovine Follicle-Stimulating Hormone", DNA, vol. 5, no. 5, pages 363-369 1986
	AY	WATKINS et al. "DNA Sequence and Regional Assignment of the Human Follicle-Stimulating Hormone beta-Subunit Gene to the Short Arm of Human Chromosome 11", DNA, vol. 6, no. 3, pages 205-212 1987
	AZ	HIRAI et al. "The gene for the beta subunit of porcine FSH: absence of consensus oestrogen-responsive element and presence of retroposons", Journal of Molecular Endocrinology, vol. 5, pages 147-158 1990
	AAA	MAURER. "Molecular Cloning and Nucleotide Sequence Analysis of Complementary Deoxyribonucleic Acid for the beta-Subunit of Rat Follicle Stimulating Hormone", Molecular Endocrinology, vol. 1, pages 717-723 1987
	AAB	GUZMAN et al. "The Gene Encoding Ovine Follicle-Stimulating Hormone beta: Isolation, Characterization, and Comparison to a Related Ovine Genomic Sequence", DNA and Cell Biology, vol. 10, no. 8, pages 593-601 1991
	AAC	KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding genes, II. Structure of the luteinizing hormone beta-subunit-encoding genes", Gene, vol. 166, pages 335-336 1995
	AAD	KUMAR et al. "Cloning of the mouse gonadotropin beta-subunit-encoding genes, I. Structure of the follicle-stimulating hormone beta-subunit-encoding gene", Gene, vol. 166, pages 333-334 1995
	AAE	STEELMAN et al. "Assay of the Follicle Stimulating Hormone Based on the Augmentation with Human Chorionic Gonadotropin", Endocrinology, vol. 53, pages 604-616 1953
	AAF	VAN HELL et al. "Effects of Human Menopausal Gonadotrophin Preparations in Different Bioassay Methods", Acta Endocrinologica, vol. 47, pages 409-418 1964
	AAG	
	AAH	
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	AAL	
	AAM	

Examiner

Date Considered

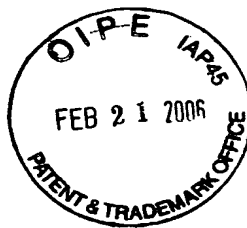
\*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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#### STATEMENT OF RELEVANCY

- 1) References AA-AD, AF-AL have been cited in the International Search Report. A copy of these references is being submitted herewith.
- 2) References AE, AM-AO have been cited in the corresponding European Search Report. A copy of these references is being submitted herewith.
- 3) References AP-AAF are discussed in the specification. A copy of these references is being submitted herewith.
- 4) References            are additional prior art known to Applicant. A copy of these references is being submitted herewith.